

Notice of Allowability	Application No.	Applicant(s)	
	09/368,076	JIN ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the Response of June 18, 2004.
2. ☒ The allowed claim(s) is/are 42-48 and 50.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| <ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date <u>6-18-2004</u> 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>7-21-2004</u> 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other _____ |
|---|--|

DETAILED ACTION

Status of the Application

1. Currently, claims 36-39, 42-48, and 50 are pending in the application. In the prior action, mailed on January 28, 2004, claims 42-50 were rejected, and claims 36-39 stood withdrawn as to non-elected inventions. In the Response filed on June 18, 2004, the Applicant amended claims 42-46, and 48; and deleted claim 49. Claims 42-48, and 50 are under consideration.
2. The Amendments to the claims requiring that they read on live-virus is noted. It is also noted that the Applicant has stated that the claims do not read on virus without any virulence. See, Response, page 5.
3. In view of the amendments to the claims in the Response, and the amendments made below in the Examiner's Amendment, claims 42-48, and 50 are allowed.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on June 18, 2004 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

EXAMINER'S AMENDMENT

5. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR

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1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Jacqueline Benn on July 21, 2004.

The application has been amended as follows:

Claims 36-39 have been cancelled from the application as drawn to non-elected inventions. ✓

Claim 48 has been amended to change its dependency from claim 46 to claim 47.

The amendment to claim 48 is to correct a lack of antecedent basis problem with reference to the language "said C-terminal truncation."

6. The following is an examiner's statement of reasons for allowance:

In addition to the reasons provided below and in the prior actions, the following considerations are also relevant to the allowance of the claims.

Claim 42 was amended in the Response by the insertion of the claim language "and wherein the truncation is less than 46 amino acids in length." The language is not considered New Matter to the Application because the specification teaches C-terminal truncations, including a truncation at position 46. Although the truncation at position 46 is obviously inoperable, and therefore excluded from the claims, there appears to be adequate support in the application for C-terminal truncations with an endpoint at 46 residues.

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It is also noted that the extent of truncation permitted by claim 42 is considered identical to the scope of truncations permitted by claim 47, which does not include the “less than 46 amino acids in length” statement. This is also due to the teachings in the application and the art indicating that truncations of 46 residues or more from the C-terminus are obviously inoperative embodiments of the described viral particles.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled “Comments on Statement of Reasons for Allowance.”

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

(Prior Rejection- Withdrawn) Claims 42, 43, and 45-49 were rejected in the prior action under 35 U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility. These claims read on isolated RSV particles with truncations of the M2-1 gene, such that a stop codon is inserted at one of a series of positions listed (e.g.) in claim 43. With the exception of the stop codons at positions 8137-8139, and 8140-8142 (representing a deletion of either 17 or 16 amino residues respectively), the Applicant has not shown adequate operability such that the Applicant is entitled to RSV particles comprising the M2-1 truncations identified in (e.g.) claim 43. The Applicant has now amended the claims to require a truncation of less than 46 amino

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acids in length, and has amended claim 43 to cancel three of the potential stop codon positions, but such that the claims still read on truncations at any of the codons at positions 8053-8055, 8137-8139, or 8140-8142. In view of the amendment of the claims removing the obviously inoperable embodiments, the rejection is withdrawn.

8. **(Prior Rejection- Withdrawn)** Claims 45-49 are rejected under 35 U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility. The claims read on RSV particles with substitutions of the M2-1 Cys3His motif. However, the art teaches that no viable viruses could be obtained when the codons encoding for the residues of this motif were mutated. The claims have now been amended such that they require the presence of the Cys3His motif. The rejection is therefore withdrawn.

Claim Rejections - 35 USC § 112

9. **(Prior Rejection- Withdrawn)** Claims 42 and 43, and 45-49 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a deletion mutant of M2-1 wherein the truncation is at amino residues 178 or 179 (nucleic acids 8137-8139 or 8140-8142 respectively), does not reasonably provide enablement for any viable truncated M2-1 protein. In particular, the claims have been rejected as lacking enablement for the deletion mutants of M2-1 wherein truncations are inserted at codon positions other than 8137-8139, or 8140-8142. In view of the cancellation of the rejected subject matter, the rejection is withdrawn.

10. **(Prior Rejection- Withdrawn)** Claim 45 was rejected in the prior action under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim was rejected for reading on embodiments of the claimed RSV comprising M2-1 proteins wherein

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the cysteine motif in the N-terminal end of the protein need not be present. In view of the amendment of claim 45, and the cancellation of claim 49, the rejection is withdrawn.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. **(Prior Rejection- Withdrawn)** Claims 42-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims read on an attenuated RSV particle that "exhibits a lower degree of virulence compared to a wild type virus." It was not clear from the claims what comprises "a wild type virus." In view of the amendment of the claims to clarify that the virus is RSV, the rejection is withdrawn.

13. **(Prior Rejection- Withdrawn)** Claim 48 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 48 recites the limitation "wherein the stop codon causing said C-terminal truncation ..." In view of the amendments made to the claim in the Response, and in the Examiner's Amendment above, the rejection is withdrawn.

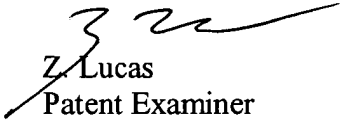
Conclusion

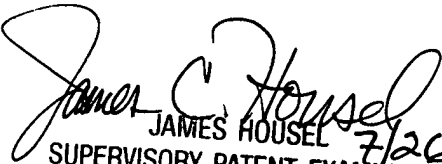
14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Z. Lucas
Patent Examiner


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